IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application No.	:	10/755,038	Confirmation No. 7887
Applicant	:	AVRAM GOLD	
Filed	:	January 9,2004	
Title	:	METHOD OF TREATING FUNCTIONAL SOMATIC SYNDROMES AND DIAGNOSING SLEEP DISORDERS BASED ON FUNCTIONAL SOMATIC SYNDROME SYMPTOMS	
Group Art Unit	:	3771	
Examiner	:	Annette F. Dixon	
Customer No.	:	28289	

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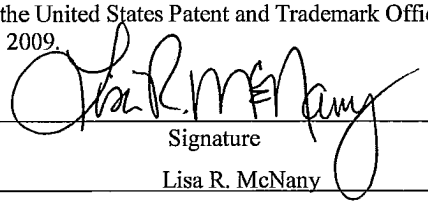
REPLY BRIEF

Sir:

In the Examiner's Answer dated July 7, 2009, the Examiner withdrew the previously-outstanding rejections and entered new grounds of rejection. In response, Appellant requests that the appeal be maintained and submits this Reply Brief addressing each of the new grounds of rejection. This Reply Brief is filed timely on September 8, 2009 as September 7, 2009 is Labor Day.

I hereby certify that this correspondence is being electronically submitted to the United States Patent and Trademark Office on September 8, 2009.

09/08/2009 
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I. STATUS OF CLAIMS

Claims 1, 5, 6, 8-12, 16, 17, 19, and 20 are pending and are the subject of this appeal.

Claims 2-4, 7, 13-15, 18, and 21-28 have been cancelled.

Claims 1, 5, 6, 11, 12, 16, and 17 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the teachings of United States Patent No. 5,954,048 to Thornton ("Thornton") in view of United States Patent No. 6,322,515 to Goor et al. ("Goor").

Claims 8, 9, 19, and 20 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the teachings of Thornton in view of Goor and further in view of United States Patent No. 6,752,766 to Kowallik et al.

Claim 10 stands rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over the teachings of Thornton in view of Goor and further in view of United States Patent No. 5,378,686 to Bennett et al.

Each of the above rejections was presented as a new ground of rejection in the Examiner's Answer mailed July 7, 2009. Goor was first cited in the Examiner's Answer.

II. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether independent claim 1 was properly rejected over the teachings of Thornton in view of Goor.

B. Whether independent claim 12 was properly rejected over the teachings of Thornton in view of Goor.

III. ARGUMENT

Despite the best efforts of several examiners over the course of nearly four years, no single reference or combination of references has been presented which establishes that the pioneering discovery described and claimed by Appellant in the subject application is obvious in view of the prior art. Most recently, as a further testament to the innovativeness of the claimed invention, the outstanding final rejections, which were based primarily on Thornton, were withdrawn. Now, new rejections based on Thornton in view of a newly cited patent to Goor are presented. However, as detailed herein, Goor fails to cure the recognized deficiencies of Thornton and, to the extent it is relevant, represents nothing more than a discussion of the sleep apnea condition in general, cumulative to that provided in other art. Thus, this latest rejection also fails to sufficiently establish that the Appellant's claimed methods of treating the functional somatic syndromes would have been a discovery obvious to one skilled in the art. Accordingly, Appellant respectfully submits that the rejection of claims 1, 5, 6, 8-12, 16, 17, 19, and 20 under 35 U.S.C. § 103(a) is improper, and all of the pending claims are allowable. Therefore, the Board is urged to reverse the Examiner's rejection of these claims over Thornton in view of Goor.

A. Claim 1 Was Not Properly Rejected Since the Required *Prima Facie* Case of Obviousness Under 35 U.S.C. § 103(a) Over Thornton in View of Goor Has Not Been Established.

Claim 1 stands rejected under 35 U.S.C. § 103(a) as being obvious over Thornton in view of Goor. For the following reasons, Appellant submits that this rejection is improper and should be withdrawn.

When making a rejection under 35 U.S.C. § 103(a), the Examiner has the burden of establishing a *prima facie* case of obviousness. *In re Fritch*, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992). Establishing a *prima facie* case of obviousness first requires the Examiner to resolve the factual inquires set forth in the case of *Graham v. John Deere Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). These inquiries include: (1) determining the scope and content of the prior art, (2) ascertaining the differences between the claimed invention and the prior art, and (3) resolving the

level of ordinary skill in the pertinent art. *Id.* at 17. Upon completing this analysis, the Examiner must then prove that, despite the differences between the prior art and the claimed invention, one skilled in the art would find it obvious to modify or combine the prior art in order to create the claimed invention. *KSR Int'l v. Teleflex, Inc.*, 82 U.S.P.Q.2d 1385, 1397 (S.Ct. 2007). This determination "must be based on consideration of the entire record, by a preponderance of evidence, with due consideration to the persuasiveness of any arguments and any secondary evidence". *Manual of Patent Examining Procedure*, (Rev. 6, Sept. 2007) § 716.01(d); *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992).

1. Scope and Content of the Prior Art

Thornton is directed to a device with an insertable oral section consisting of an upper arch and a lower arch. The arches are inserted into a user's mouth so that the upper arch engages the user's upper teeth and the lower arch engages the lower teeth. The upper arch and the lower arch are then connected by a hook and the hook forces the lower arch forward relative to the upper arch. The resulting forces cause the user's lower jaw to be positioned forward or displaced relative to the upper jaw. Such positioning of the lower jaw causes the user's breathing passageway to remain open and is known to treat certain sleep-related breathing disorders like obstructive sleep apnea and, further, snoring. A continuous positive airway pressure (CPAP) system may also be associated with or connected to the device. Adjusting the air pressure from the CPAP system can act to increase the opening of the user's breathing passageway and may be used in cooperation with the lower jaw positioning feature to treat sleep related breathing disorders such as obstructive sleep apnea and, further, snoring.

Goor is directed to a method and apparatus for the non-invasive detection of a medical condition by monitoring the peripheral arterial tone of a patient. The method can include the steps of monitoring the peripheral arterial tone using an external sensor, detecting a change in the peripheral arterial tone, and determining the physiological condition when a specific change in the peripheral arterial tone has been detected. The particular apparatus

discussed in Goor is a probe applied to the subject's digit for sensing the peripheral arterial tone and a processor for processing a signal outputted by the probe. With respect to sleep disorders, Goor postulates that the disclosed method and apparatus may be useful as an alternative means of monitoring and diagnosing sleep apnea. In the Background section, Goor mentions the existence of different types of obstructive sleep disordered breathing. Particularly, Goor contrasts obstructive sleep apnea, characterized by the frank cessation of breathing, with hypopnea and upper airway resistance syndrome (UARS), which do not involve complete obstruction of the upper airway but can nonetheless result in frequent arousals from sleep. Goor acknowledges that UARS is associated with a more subtle symptomatology and is thus much more difficult to diagnose. Additionally, in column 36, Goor discusses a study involving 42 patients with obstructive sleep apnea in which a profound, transient attenuation of the pulse arterial tone (PAT) signal and tachycardia, usually of a periodic nature, were clearly seen with each apneic event.

2. Differences Between the Prior Art and the Claimed Invention

Claim 1 is directed to a method of treating functional somatic syndromes by: determining whether a patient suffers from inspiratory airflow limitation during sleep; identifying the patient as suffering from a functional somatic syndrome; and treating the patient with an upper airway stabilization technique. Appellant's claimed method is based on his pioneering recognition and discovery that inspiratory airflow limitation during sleep demonstrably plays a primary role in development of the functional somatic syndromes and, as a result, treatment of inspiratory airflow limitation via an upper airway stabilization technique, like positive airway pressure therapy as one provided example, "improves the symptoms/signs associated with the functional somatic syndromes". (Specification, Paragraph [0066]). Accordingly, Appellant alone identifies a causal connection between inspiratory airflow limitation during sleep and the functional somatic syndromes and further teaches the corrective regimen of upper airway stabilization, whether by mechanical means and/or positive airway pressure therapy means, and the like.

As described by Appellant, functional somatic syndromes are defined as "physical syndromes without an organic disease explanation, demonstrable structural changes, or established biochemical abnormalities". (Specification, Paragraph [0005]). A patient suffering from a functional somatic syndrome is usually characterized more by symptoms than by demonstrable and identifiable physical abnormalities. *Id.* Functional somatic syndromes, then, are a unique class of disorders for which current medical science has been unable to identify a unifying underlying cause. The foregoing definition of the functional somatic syndromes is corroborated by Dr. Mark Sanders, an expert in the field of Sleep Medicine, in his Declaration Under 37 C.F.R. § 1.132 ("Sanders Declaration") submitted on May 21, 2007. Dr. Sanders states that, "[Appellant's] disclosure correctly identifies a definition of functional somatic syndromes...that comports with the medical literature relating to functional somatic syndromes." (Sanders Declaration, Paragraph 5).

It is readily apparent from a close inspection of Thornton and Goor that these references fail to teach or suggest any possible causal connection or linkage between restricted or limited inspiratory airflow during sleep and the functional somatic syndromes which may be addressed via upper airway stabilization pursuant to Appellant's disclosure. In fact, these patents fail to discuss or even mention the functional somatic syndromes at all. As mentioned above, a medically accepted definition of the functional somatic syndromes is physical syndromes without an organic disease explanation, demonstrable structural changes, or established biochemical abnormalities. Thornton's teachings, on the other hand, are limited to treatment of a patient suffering from disorders caused by a collapsed airway, such as obstructive sleep apnea and snoring. Thornton is not directed to the treatment of the functional somatic syndromes. In fact, the Examiner's Answer appears to confirm this deficiency in stating: "Thornton does not expressly disclose an explicit correlation between the symptoms of functional somatic syndrome and sleep apnea." (Examiner's Answer, page 9).

Goor, like Thornton, also fails to discuss or mention the functional somatic syndromes or the treatment thereof. Rather, Goor suggests a relationship between the peripheral arterial tone and sleep staging, as well as the use of the disclosed finger probe as a simpler means

for sleep staging and detection of sleep apnea. (*See* Goor, column 7, lines 12-15; column 27, line 44 through column 29, line 10). Like in Thornton, Goor is limited to detecting disorders caused by a known and demonstrable structural change in the patient and specifically a collapsed airway, such as obstructive sleep apnea, albeit by the purportedly unconventional method of monitoring the peripheral arterial tone.

Only Appellant identifies the primary role of inspiratory airflow limitation during sleep and the functional somatic syndromes (Specification, Paragraph [0057]) and identifies corrective action or treatment of the inspiratory airflow limitation to modify the symptoms of functional somatic syndromes. (Specification, Paragraph [0056]). Obstructive sleep apnea and other similar disorders such as snoring, on the other hand, are commonly known to be caused by a fully or partially collapsed airway. Such sleep-disordered breathing has never been considered by those skilled in the art to be a functional somatic syndrome and is not part of any medical listing known to Appellant identifying or grouping the functional somatic syndromes. Treating patients known to experience a collapsed airway during sleep through the use of an oral device or positive airway pressure therapy is common in the Sleep Medicine field and is generally the subject of the Thornton reference. Appellant does not contest that the Thornton device is suitable for use in treating obstructive sleep apnea, snoring, and the like and may even be used in Appellant's claimed method for treating functional somatic syndromes as the Thornton device conventionally relieves, at least partially, an obstructed airway. However, it is abundantly clear from the plain text of Thornton that the disclosed CPAP-aided oral device is not directed to, nor is there any relevant teaching or suggestion in Thornton for, the treatment of the functional somatic syndromes.

Reference to the Goor patent fails to cure this deficiency in Thornton because Goor also fails to teach or suggest a link between inspiratory airflow limitations and the functional somatic syndromes. While the Examiner's Answer correctly recites Goor's statement that sleep apnea is "characterized by repetitive episodes of upper airway collapse during sleeping resulting in interrupted airflow despite persistent respiratory effort" (Goor, column 6, lines 52-54) and obstructive sleep apnea is associated with "progressively increasing asphyxia until

termination by a brief arousal from sleep and restoration of upper airway patency" (Goor, column 6, lines 56-57), these statements in Goor represent nothing more than well known observations about obstructive sleep apnea in general. These statements do not speak of the functional somatic syndromes, nor do they provide relevant teachings or suggestions for the treatment of these syndromes or a link between these syndromes and limited inspiratory airflow during sleep. Rather, these statements simply provide background commentary regarding Goor's disclosure of an improved way of detecting obstructive sleep apnea through the use of a finger probe.

It is the Appellant that has first identified the primary role of inspiratory airflow limitation during sleep and the functional somatic syndromes and proposed and developed a treatment regime in the form of stabilizing a patient's upper airway with positive airway pressure therapy and/or mechanical stabilization as specific examples. This discovery and methodological treatment implementation is a pioneering recognition and development in the medical field completely unrecognized by Thornton and Goor directly or through reasonable implication or derivation of their teachings. Further evidence of this fact can be found in the Sanders Declaration. Dr. Sanders, a recognized expert in the field of Sleep Medicine, states that, "[t]he device disclosed in Thornton is intended to treat sleep disordered breathing such as snoring and sleep apnea using positive airway pressure therapy. The device is not intended to or disclosed in any way as being suitable for treating functional somatic syndromes." (Sanders Declaration, Paragraph 8).

With the foregoing in mind, upon comparing the scope and content of the applied art and the claimed invention as embodied in claim 1, it can only be concluded that there are fundamentally distinct and irreconcilable differences between the subject matter of claim 1 and the applied art. First and foremost, both Thornton and Goor are utterly silent on the subject of functional somatic syndromes, failing to mention the functional somatic syndromes (expressly or by implication) or patients suffering therefrom, much less a potential causal link between inspiratory airflow limitation during sleep and these syndromes. By extension, it is clear that Thornton and Goor do not (or cannot) disclose or suggest a step of identifying a patient

determined to be suffering from inspiratory airflow limitation during sleep as having a functional somatic syndrome. Moreover, Thornton, whether considered alone or in view of Goor, completely fails to teach or suggest a step of treating a patient identified as having a functional somatic syndrome with an upper airway stabilization technique. The same can be said for Goor, which is not directed to treatment at all. This step is based on Appellant's pioneering discovery that the functional somatic syndromes can be successfully treated through stabilization of a patient's upper airway with positive airway pressure therapy and/or mechanical stabilization as specific examples. The conventional obstructive sleep apnea/snoring treatment apparatus disclosed by Thornton is limited to treating a patient suffering from sleep-disordered breathing of known causation (*i.e.*, a fully or partially collapsed airway) with a conventional oral device optionally coupled with continuous positive airway pressure therapy. Goor does not discuss airway pressure therapy at all, and instead is limited to a method of non-invasively determining a physiological condition, such as sleep apnea, by monitoring the peripheral arterial tone in a patient's finger.

3. The Level of Ordinary Skill in the Pertinent Art

The foregoing enumerated differences between the Thornton disclosure and the subject matter of claim 1 are confirmed by Dr. Sanders (in his Declaration), who, as a medical doctor primarily practicing in the field of Sleep Medicine, is clearly one of ordinary skill in the pertinent art. Dr. Sanders states in his Declaration that, "[t]he device disclosed in Thornton is intended to treat sleep disordered breathing such as snoring and sleep apnea...[and] is not intended to or disclosed in any way as being suitable for treating functional somatic syndromes." (Sanders Declaration, Paragraph 8.) Dr. Sanders further confirms that "Thornton does not disclose or suggest a possible relationship between inspiratory airflow limitation during sleep and the functional somatic syndromes". *Id.* While Appellant has not had the opportunity to allow a skilled artisan to opine on the newly cited Goor patent, considering that Goor's discussion of sleep disorders is confined to sleep apnea and no mention is made of the functional somatic syndromes, it can be said that Goor also fails to disclose or suggest a possible

relationship between inspiratory airflow limitation during sleep and the functional somatic syndromes. Accordingly, it is clear fundamental differences exist between the teachings of Thornton, alone or in view of Goor, and the subject matter recited by Appellant in claim 1.

4. The Examiner's Answer Fails to Support the Rejection of Claim 1 Under 35 U.S.C. § 103(a) Over Thornton in View of Goor

In order for an invention to be properly rejected under 35 U.S.C. § 103(a), there must be an explicit rationale explaining why, despite the differences between the applied art and the claimed invention, the claimed invention would have been obvious to one of ordinary skill in the art. *KSR*, 82 U.S.P.Q.2d at 1396. Because there has been no explicit rationale offered in the Examiner's Answer that explains why Appellant's claimed method, as embodied in claim 1, would have been obvious over the Thornton and Goor patents despite the distinct differences present between the subject matter of claim 1 and these patents, the rejection of claim 1 must be reversed.

As explained previously, Appellant has discovered a pioneering causal link between inspiratory airflow limitation during sleep and the functional somatic syndromes. This pioneering discovery led Appellant to develop a treatment method in which a patient determined to be suffering from inspiratory airflow limitation and identified as having a functional somatic syndrome is treated with an upper airway stabilization technique such as positive airway pressure therapy as one example. On the other hand, Thornton is limited to the conventional treatment of obstructive sleep apnea and snoring, disorders of known causation, through the use of a conventional lower jaw repositioning oral device optionally coupled with a continuous positive airway pressure system and Goor is limited to a method of monitoring sleep conditions through the detection of the peripheral arterial tone in the digit of a patient. In view of these clear differences enumerated previously between Thornton, Goor, and claim 1, the Examiner's Answer fails to provide a satisfactory explanation as to why, despite the differences between the applied art and the claimed invention, the claimed invention would have been obvious to one of ordinary skill in the art.

In the Examiner's Answer, it is contended that since Thornton teaches his oral device is for treating breathing disorders, and Appellant has listed sleep apnea and snoring as disorders/diseases that are considered functional somatic syndromes, Thornton teaches a device capable of providing treatment for a functional somatic syndrome. (Examiner's Answer, page 5). While the Examiner's Answer admits that Thornton fails to disclose a correlation between the symptoms of the functional somatic syndromes and sleep apnea, and thus apparently fails to suggest a step of identifying a patient suffering from inspiratory airflow limitation during sleep as having a functional somatic syndrome, it is alleged a correlation between the symptoms of the functional somatic syndromes and sleep apnea was well known, as evidenced by Goor. (*Id.* at 6). In this regard, it is asserted that a physician, upon identifying the symptoms associated with a patient suffering from airflow limitation during sleep, would treat the patient with Thornton's device and would utilize the information about the symptoms and treatment in order to diagnose the patient as having a functional somatic syndrome. (*Id.* at 6).

The foregoing reasoning fails on several accounts. First, Appellant has not, in fact, listed obstructive sleep apnea and snoring as disorders or diseases that are considered functional somatic syndromes. Appellant discussed obstructive sleep apnea and snoring in connection with a method of diagnosing *sleep disorders in general*, of which obstructive sleep apnea and snoring may be a symptom. (Specification, Paragraphs [0014-0015]). This method was the subject of original claims 21-28, which are not part of this appeal. Thus, the very foundation of the reasoning present in the Examiner's Answer in support of the rejection of claim 1 is fundamentally flawed and based on an incorrect reading of Appellant's disclosure relating to a method of diagnosing sleep disorders which may stem concurrently from Appellant's work in the field of functional somatic syndromes. This diagnostic method has been identified in the prosecution as a patentably distinct concept from the method addressed in claim 1 and was the subject matter of a Restriction Requirement issued on August 16, 2005. In response to this Restriction Requirement, Appellant elected to pursue the subject matter of independent claims 1 and 12 rather than the concept embodied in original claims 21-28. The

diagnostic method in original claims 21-28 is not the subject of this Appeal and is now properly the subject of a divisional application.

Second, whether or not the Thornton device is *capable* of treating a functional somatic syndrome is of no consequence to the patentability of the method claimed in claim 1. Claim 1 is directed to a method of treating functional somatic syndromes which may include a treatment device much like that disclosed by Thornton. Thornton discloses the use of an oral device optionally in conjunction with positive airway pressure therapy to treat obstructive sleep apnea and snoring. That this device is capable of being used in other, unknown methods does not render these new methods unpatentable since a new use of a known device is clearly patentable. 35 U.S.C. §§ 100-101; *see also In re King*, 801 F.2d 1324, 1327, 231 U.S.P.Q. 136, 138 (Fed.Cir. 1986) (affirming that "the discovery of a new use for an old structure based on unknown properties of the structure" could be "patentable to the discoverer as a process"). There is nothing in Thornton that would teach one skilled in the art to treat the functional somatic syndromes with an airway stabilization technique. Dr. Sanders particularly noted in this regard that "[t]he device disclosed in Thornton is intended to treat sleep disordered breathing such as snoring and sleep apnea...[and] is not intended to or disclosed in any way as being suitable for treating functional somatic syndromes." (Sanders Declaration, Paragraph 8.) Dr. Sanders further confirms that "Thornton does not disclose or suggest a possible relationship between inspiratory airflow limitation during sleep and the functional somatic syndromes". *Id.* Dr. Sanders concludes by stating that until Appellant's recent disclosure, the use of a CPAP device to treat functional somatic syndromes was unknown and, consequently, untried and such a device would not have been used by one skilled in the art to treat a functional somatic syndrome, and it would be non-obvious to do so. *Id.*

The Examiner's Answer is also incorrect to the extent it suggests Goor teaches a correlation between the functional somatic syndromes and inspiratory airflow limitation during sleep. As explained previously, Goor is in no way directed to the treatment and diagnosis of functional somatic syndromes. Instead, Goor teaches recognition of sleep apnea by monitoring the peripheral arterial tone of a patient. While Goor does make the general statement that sleep

apnea patients suffer from repetitive episodes of upper airway collapse during sleep, it does not necessary follow that a physician would characterize such a patient as having a functional somatic syndrome or symptom thereof. Instead, following Goor, the patient would likely be identified as suffering from sleep apnea. As explained above, sleep apnea is not considered to be a functional somatic syndrome since it is caused by a demonstrable and recognized structural change, namely, a collapsed airway. Accordingly, Goor fails to disclose any connection between inspiratory airflow limitation during sleep and the functional somatic syndromes.

Without knowledge of the relationship between inspiratory airflow limitation and the functional somatic syndromes, which according to Dr. Sanders is not common medical knowledge in the field of Sleep Medicine, a physician would neither identify a patient suffering from inspiratory airflow limitation during sleep as having a functional somatic syndrome nor treat that patient with one or more upper airway stabilization techniques. Nonetheless, the Examiner's Answer appears to assume that a physician would not only treat a patient identified as suffering from inspiratory airflow limitations during sleep with the Thornton device, but would also utilize this information to arrive at a diagnosis of a functional somatic syndrome. Fundamentally, the Examiner's Answer makes a leap in logic that a recognized expert in the field of Sleep Medicine declares is not present. Only Appellant's disclosure provides the relationship between inspiratory airflow limitations during sleep and the functional somatic syndromes. This relationship is not present in either Thornton or Goor.

In light of the foregoing remarks, the Examiner's Answer fails to set forth a *prima facie* case of obviousness as to claim 1. In view of the differences between the claimed subject matter and the applied art and lack of supporting rationale in the Examiner's Answer which does not explain with the requisite degree of clarity why one skilled in the art would find the method of treating functional somatic syndromes recited in claim 1 obvious, the rejection of claim 1 should be reversed.

B. Claim 12 Was Not Properly Rejected Since the Required *Prima Facie* Case of Obviousness Under 35 U.S.C. § 103(a) Over Thornton in View of Goor Has Not Been Established.

Claim 12 also stands rejected under 35 U.S.C. § 103(a) for obviousness over Thornton in view of Goor. Appellant respectfully submits that the Examiner's Answer fails to establish a *prima facie* case of obviousness of claim 12 over Thornton in view of Goor and the rejection of this claim should also be reversed.

1. Scope and Content of the Prior Art

Because claim 12 stands rejected over Thornton in view of Goor as applied to claim 1, the first inquiry under the *John Deere* factors is the same as discussed *supra* in Section III. A. 1.

2. Differences Between the Prior Art and the Claimed Invention

Claim 12 is directed to a method of treating functional somatic syndromes by: determining whether a patient suffers from inspiratory airflow limitation during sleep; identifying the patient as suffering from one or more symptoms of a functional somatic syndrome; and treating the patient with an upper airway stabilization technique. This method, like the method recited in claim 1, is based on Appellant's pioneering recognition and discovery that inspiratory airflow limitation during sleep demonstrably plays a primary role in development of the functional somatic syndromes and, as a result, treatment of inspiratory airflow limitation via an upper airway stabilization technique can be used to improve the symptoms associated with the functional somatic syndromes. Because functional somatic syndromes are disorders not usually associated with a known and identifiable physical abnormality, a patient suffering from a functional somatic syndrome or syndromes is often more easily identified by the physical symptoms he or she experiences than by any demonstrable structural change or organic disease. (Specification, Paragraph [0005]). Examples of some of the symptoms most commonly associated with a functional somatic syndrome have been provided by Appellant, though one

skilled in the art would understand this list to be non-exhaustive. (Specification, Paragraph [0011]). Appellant's pioneering discovery of a causal linkage between restricted or limited inspiratory airflow during sleep and the functional somatic syndromes has led to the development of the treatment method set forth in claim 12, which is slightly modified from claim 1, as this claim specifically calls out for identifying "symptom(s)" of a functional somatic syndrome. Appellant's claim 12 identifies that once inspiratory airflow limitation during sleep is determined and one or more symptoms of a functional somatic syndrome is identified, the patient can be treated with an upper airway stabilization technique, such as positive airway pressure therapy in one embodiment.

Appellant's previous comments concerning Thornton and Goor respective to claim 1 are equally applicable to claim 12 and are incorporated herein by reference. As both Thornton and Goor clearly fail to teach or suggest any potential causal connection or linkage between inspiratory airflow limitation during sleep and the functional somatic syndromes, it is readily apparent that these references are likewise silent with respect to "symptoms" associated with the functional somatic syndromes according to claim 12. Accordingly, from the text of Thornton, it is abundantly apparent that the oral device disclosed therein is not directed to the treatment of a patient identified as having one or more symptoms of a functional somatic syndrome, which symptoms are completely unique from the symptoms associated with the disorders treated in Thornton, namely obstructive sleep apnea and snoring. Moreover, Goor fails to cure the deficiency of Thornton in this regard, and instead only discusses sleep apnea in general, as well as a method of detecting sleep apnea by monitoring the peripheral arterial tone of a patient. Appellant's discovery that a patient identified as suffering from one or more symptoms of a functional somatic syndrome can be treated through stabilization of the patient's upper airway with, for example, positive airway pressure therapy is a pioneering recognition in the medical field that is completely unrecognized by Thornton, whether considered alone or in combination with Goor, either directly or through reasonable implication of their teachings.

In light of the foregoing comments, upon comparing the scope and content of the applied art and the claimed invention as embodied in claim 1, it is clear that there are

fundamentally distinct and irreconcilable differences between the subject matter of claim 12 and the same applied art. With respect to claim 12, as noted previously in connection with claim 1, Thornton and Goor are both utterly silent on the subject of functional somatic syndromes, failing to mention the functional somatic syndromes (expressly or by implication) or patients suffering therefrom and, moreover, are completely silent regarding any "symptoms" which could be implied to be related to one or more of the functional somatic syndromes. Thornton does not even mention specific "symptoms" associated with obstructive sleep apnea and snoring which are ailments which the disclosed oral device is intended to treat. Without even enumerating a single such "symptom" one skilled in the art could not then even arguably extrapolate to a "symptom" of the functional somatic syndromes from the Thornton disclosure. Moreover, Thornton completely fails to teach or suggest a step of treating a patient identified as having one or more symptoms of a functional somatic syndrome with an upper airway stabilization technique. Furthermore, Thornton completely fails to teach or suggest a step of treating a patient identified as having one or more symptoms of a functional somatic syndrome with an upper airway stabilization technique since this step is based on Appellant's pioneering discovery that the functional somatic syndromes can be successfully treated through stabilization of a patient's upper airway with positive airway pressure therapy and/or mechanical stabilization as specific examples.

3. The Level of Ordinary Skill in the Pertinent Art

Appellant's comments in Section III. A. 3. are incorporated herein by reference.

4. The Examiner's Answer Fails to Support the Rejection of Claim 12 Under 35 U.S.C. § 103(a) Over Thornton in View of Goor

Because there has been no explicit rationale offered in the Examiner's Answer that explains why Appellant's claimed method, as embodied in claim 12, would have been obvious over Thornton in view of Goor despite the distinct differences present between the subject matter of claim 12 and the cited art, the rejection of claim 12 must be reversed.

As explained previously in connection with claim 1, Appellant has discovered a pioneering causal link between inspiratory airflow limitation during sleep and the functional somatic syndromes. This pioneering discovery led Appellant to develop a treatment method in which a patient determined to be suffering from inspiratory airflow limitation and identified as having a functional somatic syndrome is treated with an upper airway stabilization technique such as positive airway pressure therapy as one example. Claim 12 extends this pioneering link to identifying one or more symptoms of a functional somatic syndrome rather than the syndrome itself but is otherwise similar in scope to claim 1. The rationale presented with respect to claim 12 is essentially repeated from the treatment provided to claim 1.

Because the rationale applied in the Examiner's Answer in rejecting claim 12 mirrors that provided in the rejection of claim 1, Appellant incorporates herein the arguments presented *supra* in Section III. A. 4. Appellant submits that the rationale presented in the Examiner's Answer in rejecting claim 12 suffers from the same deficiencies as that offered in rejecting claim 1 since, as previously explained, Thornton and Goor fail to disclose or suggest any potential link between inspiratory airflow limitation during sleep, one or more symptoms of the functional somatic syndromes, and a treatment method using upper airway stabilization. Consequently, Appellant's previous arguments are adequate to establish that the rejection of claim 12 should also be reversed and will not be repeated here.

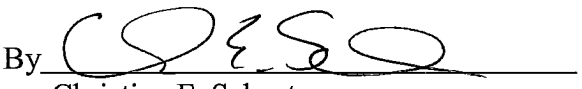
In light of the foregoing remarks, the Examiner's Answer fails to set forth a *prima facie* case of obviousness as to claim 12. In view of the differences between the claimed subject matter and the applied art and lack of supporting rationale in the Examiner's Answer which does not explain with the requisite degree of clarity why one skilled in the art would find the method of treating functional somatic syndromes recited in claim 12 obvious, the rejection of claim 12 should be reversed.

CONCLUSION

In view of the foregoing, it is respectfully submitted that the rejection of claims 1, 5, 6, 8-12, 16, 17, 19, and 20 under 35 U.S.C. § 103(a) is improper and all of the pending claims are allowable. Appellant therefore respectfully urges the Board to reverse the Examiner's rejection of these claims over Thornton in view of Goor, presented for the first time in the Examiner's Answer and direct the issuance of a Notice of Allowability.

Respectfully submitted,

THE WEBB LAW FIRM

By 

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